THE QUEEN'S MEDICAL CENTER

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October 24, 2002

USNRC Region IV
Attention: Louis Carson
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Greetings:

The attached report regards our Intravascular Brachytherapy misadministration on 10/9/02. It is submitted pursuant to 10 CFR 35.33. Please call me directly at (808) 547-4884 if you require additional information.

Best Regards,

Scott Dube

Scott Dube, M.S.
Radiation Safety Officer

Licensee The Queen's Medical Center, License Number 53-16533-02

Authorized User Vincent Brown, M.D.

Event On 10/9/02, the patient was to be treated with Intravascular Brachytherapy (IVB) using the Novoste BetaCath system. The intent was to deliver 18.4 Gy to the left anterior descending (LAD) artery. Following the established procedure, the treatment segment of the BetaCath was positioned in the catheter using fluoroscopy. The source train was then deployed into the patient. The radiation oncologist and cardiologist were certain they could see the proximal and distal markers of the source train on the fluoroscopy monitor. Based on this information, the physicist did not make a survey to confirm the source train was in the chest. The treatment proceeded with fluoroscopy checks every 30 seconds.

At the end of treatment, the radiation oncologist attempted to return the source train. However, some of the sources did not return to the device. So, the train was deployed a second time followed by an attempt to return the sources. The second attempt failed. Consequently, the cardiologist pulled the entire catheter out of the patient and placed it in the "bail out box". The physicist confirmed all sources were retracted visually as well as by survey.

Upon closer inspection, the radiation oncologist discovered a kink in the catheter where the distal seed and marker were stuck. He manipulated the catheter until the entire source train could be returned to the device.

The kinked catheter raised concern about the source delivery so the radiation oncologist and physicist looked at the cine pictures to verify the distal and proximal markers. While the distal marker was clearly seen, the proximal marker was not. Further inspection of the cine images in magnification mode revealed only one active seed reached the proper location while five seeds were positioned in the beginning LAD and ten seeds were located outside the cine field of view during treatment.

Cause The entire source train did not reach the treatment site because of a kink in the catheter. This was not apparent to the radiation oncologist and cardiologist who thought they could see the source train markers on the fluoroscopy image.

Effect The 18.4 Gy was not delivered to the prescribed section of the LAD. Therefore, the risk of restenosis was not reduced by the procedure. Instead, the dose was delivered to an unintended section of the LAD and aorta. It is unlikely there will be any adverse effect from this dose.

Improvements to prevent recurrence It has been the responsibility of the radiation oncologist and cardiologist to verify the positions of the distal and proximal markers on the fluoroscopy image. We shall now require verification by the radiological technologist and medical physicist as well. Each of their affirmations will be documented on the procedural Safety Record form.

Actions to prevent recurrence The revised procedure will be implemented immediately.

Patient Notification The patient was told after the procedure that some of the sources were positioned in the wrong section of the catheter. A copy of this report has been sent to the patient as well.

Submitted Scott Dube, Radiation Safety Officer on 10/24/02